Idaho Medicaid – Prior Authorization Therapeutic Criteria Hepatitis C Agents
Pharmacy & Therapeutics Committee
Approved April 15, 2016

DRUG NAME:
Daclatasvir (Daklinza ™)
Elbasvir/Grazoprevir (Zepatier™)
Ledipasvir/Sofosbuvir (Harvoni™)
Ombitasvir/Paritaprevir/Ritonavir (Technivie™)
Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir (Viekira PAK™)
Simeprevir (Olysio®)
Sofosbuvir (Sovaldi®)

Prior authorization form available at website:
http://www.healthandwelfare.idaho.gov/Portals/0/Medical/PrescriptionDrugs/Hepatitis-C%20Agents.doc

COVERED USES:
Treatment of FDA approved indications for chronic hepatitis C (HCV) infection.

AGE RESTRICTIONS:
FDA approved for ages 18 years or older.

PRESCRIBER RESTRICTIONS:
Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

INCLUSION CRITERIA (All criteria must be met):
- FDA approved HCV genotypes for chronic infection or hepatic carcinoma secondary to HCV awaiting liver transplantation.
- Liver Biopsy with a (Metavir stage F3-F4) or Batts-Ludwig scale 3-4 OR Fibroscan measurement >12.5 kPa OR ARFI value >1.75 meters/second OR radiographic imaging (CT/MRI) with features of portal hypertension, ascites, and hepatosplenomegaly OR APRI score >1.5 OR FIB-4 > 3.25 and serious extrahepatic manifestations of hepatitis C .
- Prescribed within the FDA approved indications/combinations/doses.
- Under the care of and/or collaboration with an experienced HCV practitioner.
- Documentation that the provider has discussed with patient the potential risks and benefit of HCV therapy and progression of HCV disease and a shared decision has been made for antiviral treatment.
- Adherence counseling performed and documented understanding of compliance to treatment by patient.
- Patient has no history of alcohol or substance abuse within the 6 months prior to treatment or has documented evidence of successful completion of 6 months of abstinence for injection drug use and/or substance abuse/alcohol dependency (if applicable)
- Negative urine toxicology and Ethyl Glucuronide (EtG) alcohol screening test within 1 month of request.

- Required testing for resistance polymorphism prior to treatment:
    - Daclatasvir (Daklinza™): Genotype 1a patients with cirrhosis, consider testing for the presence of virus with NS5A polymorphisms at amino acid positions M28, Q30, L31, and Y93.
    - Simeprevir (Olysio®): Genotype 1a, prior to initiation, test for the presence of virus with NS3 Q80K polymorphism; sustained virologic response rates may be lower and other treatments should be considered
    - Elbasvir/Grazoprevir (Zepatier™): Presence of virus with NS5A resistance-associated polymorphisms, in patients with genotype 1a infection; prior to initiation

EXCLUSION CRITERIA:

- Non-FDA approved indications/drug combinations/dosing regimens.
- Agents not FDA approved for decompensated liver disease.
- Prior authorization requests that have incomplete documentation with no follow up response within 30 days of submission.
- Patients with chronic HCV with minimal fibrosis (Metavir stage F0-F2).
- For agents prescribed in combination with ribavirin: pregnant women or those who may plan to become pregnant during the course of treatment.
- Documented ongoing non-adherence to prior medications, medical treatment or failure to complete HCV disease evaluation appointments and procedures or patient is unable to commit to scheduled follow-up/monitoring for the duration of treatment.
- Documented active history of intravenous drug abuse/alcohol dependency/substance abuse.
- Known hypersensitivity to any component of agent requested.
- Hepatitis C agents not recommended in patients with a history of relapse.
- Co-administration with drugs that are contraindicated with hepatitis C agent requested.
- Clinical contraindications for the use of hepatitis C agents per manufactures recommendations:
    - Moderate to severe hepatic impairment (Child-Pugh B or C) for Viekira PAK™/ Zepatier™.
    - Severe renal impairment (eGFR less than 30ml/min/1.73m^2) or hemodialysis (Sovaldi® / Harvoni™.
    - Patients with HCV genotype 4 with cirrhosis. (Technivie™)

REQUIRED MEDICAL INFORMATION:

- Diagnosis of chronic hepatitis-C infection (ICD-10 B18.2) with confirmed genotype of 1, 2, 3, 4, or 6 or diagnosis of hepatic carcinoma secondary to HCV awaiting liver transplantation.
- Documented evidence of fibrosis (Metavir score F3- F4) OR (Batts-Ludwig scale 3-4) OR Fibroscan measurement >12.5 kPa OR ARFI value >1.75 meters/second OR radiographic imaging (CT/MRI) with features of portal hypertension, ascites, and hepatosplenomegaly OR APRI score >1.5 OR FIB-4 > 3.25 and serious extrahepatic manifestations of hepatitis C.
    - Note: FibroSure®, FibroTest®, and FIBROSpect® are not recommended for routine use in the diagnosis of cirrhosis. Confirmation with CT scan or liver biopsy is required.
- Documentation of recent laboratory values, within 6 months of request, including LFT's, CBC, genotype, HCV RNA viral count, testing for resistance polymorphism and negative pregnancy test (if applicable).
- Patients with a history of intravenous drug/substance abuse/alcohol dependence will require documentation of successful completion of 6 months of abstinence for injection drug/substance abuse and/or alcohol dependency.

- A random urine toxicology and Ethyl Glucuronide (EtG) alcohol screening within 1 month of request.
- Previous history of HCV treatment (treatment naïve or treatment experienced).
- Documentation of interferon ineligibility (if applicable).

COVERAGE DURATION:

- FDA approved treatment regimens/durations.

TREATMENT/MONITORING CRITERIA:

- Healthcare provider must submit a HCV -RNA viral count prior to 4 weeks of treatment for all genotype treatments to determine compliance and efficacy of treatment.
- Healthcare provider must submit a HCV -RNA viral count at weeks 8 and 12 for all 12-WEEK TREATMENTS.
- Healthcare provider must submit a HCV-RNA viral count at weeks 8, 12, and 16 for all 16-WEEK TREATMENTS.
- Healthcare provider must submit a HCV- RNA viral count at weeks 8, 12, and 24 for all 24-WEEK TREATMENTS.
- Requests for renewal will be denied in patients who have not achieved HCV-RNA below the limit of detection after 4 weeks of therapy or in patients who have not demonstrated a 1-log decrease in HCV RNA (response) after 4 weeks.
- All treatment must be discontinued if HCV RNA is >25 IU/ml at week 4 or at any other time point thereafter.
- Drug treatment approval will be denied if there is a discontinuation or dose reduction of any component of combination treatment plan.
- Patients with a history of substance/alcohol abuse will require monthly random urine toxicology and/or Ethyl Glucuronide (EtG) alcohol screening while on treatment.
- Healthcare provider must submit a sustained viral response (SVR) at week 12 and week 24 after successful completion of treatment.

OTHER:

The criteria for Hepatitis C agents are based upon the most current evidence provided. Newer agents not reviewed by the Pharmacy & Therapeutics Committee will be evaluated on a case-by-case basis. Idaho Medicaid recognizes as new information becomes available, these criteria may change and revised if necessary.

REFERENCES:

Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations.
From the Department of Veterans Affairs National Hepatitis C Resource Center Program and the National Hepatitis C Resource Center Program and National Viral Hepatitis Program in the Office of Patient Care Services Updated March 28, 2016. http://www.hepatitis.va.gov/pdf/treatment-considerations-2016-03-28.pdf

AASLD-IDSA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. February 24,2016 Update. Accessed 4/7/2016.

Product Information: SOVALDI® oral tablets, sofosbuvir oral tablets. Gilead Sciences (per manufacturer), Foster City, CA, 2015.

Product Information: HARVONI® oral tablets, ledipasvir, sofosbuvir oral tablets. Gilead Sciences Inc. (per manufacturer), Foster City, CA, 2016.

Product Information: OLYSIO® oral capsules, simeprevir oral capsules. Janssen Products (per FDA), Titusville, NJ, 2015.

Product Information: VIEKIRA PAK oral tablets, ombitasvir paritaprevir ritonavir oral tablets and dasabuvir oral tablets. AbbVie Inc. (per manufacturer), North Chicago, Il, 2014.

Product Information: DAKLINZA™ oral tablets, daclatasvir oral tablets. Bristol-Myers Squibb Company (per manufacturer), Princeton, NJ, 2016.

Product Information: TECHNIVIE™ oral tablets, ombitasvir paritaprevir ritonavir oral tablets. AbbVie Inc. (per Manufacturer), North Chicago, IL, 2015.

Product Information: ZEPATIER(TM) oral tablets, elbasvir, grazoprevir oral tablets. Merck Sharp & Dohme Corp. (per manufacturer), Whitehouse Station, NJ, 2016.